SEP 1 2 2001

ATTACHMENT 1(b)

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) **Submitter's name, address, telephone number, contact person:**

Gary J. Allsebrook (510) 276-2648
Regulatory Affairs
Regulatory Management Services.
16303 Panoramic Way
San Leandro CA 94578-1116
Telephone: (510) 276-2648
Facsimile: (510) 276-3559

Prepared: March 6, 2001

2) **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/Usual Name:
Diagnostic Ultrasound System and Accessories
Multiplane Transesophageal Ultrasound Transducer
Intra-operative Ultrasound Transducer

Proprietary Name:
SonoAce 9900 Diagnostic Ultrasound System and Transducers.
Multiplane Transesophageal Ultrasound Transducer (MPT4-7AL)
Intra-operative Ultrasound Transducers (LI5-9EV, CL4-8EV)

Classification Names:	FR Number	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) **Identification of the predicate or legally marketed device:**

Medison believes that the SA9900 Ultrasound system are substantially equivalent to the currently marketed SA8800/HDI1500 System (K974269).

4) Device Description:

The SA 9900 scanner is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B-mode, M-mode, Color-Flow Doppler, Continuous (CW) Doppler, Pulsed (PW) Doppler, Power Doppler, and 3D imaging or as a combination of these modes. The SA 9900 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed. All modes of operation have been previously cleared in 510(k) K002185. The system also provides for the measurement of anatomical structures and for analysis packages that provide information used for clinical diagnostic purposes by competent health care professionals. The control panel has not changed from the description in the SA9900 Ultrasound System Operator's Manual, submitted in the 510(k) Special Report, Add-to-File for K002185.

Various different models of transducers are available and any four may be connected at the same time. In addition to the initial operational settings for each transducer preprogrammed in the system, user-customized parameter settings for each transducer may be inserted by the operator and stored for recall as needed via the system control panel. Customization includes transmit focusing, filtering, image enhancement processing, dynamic window curve selection. Controls are also provided to select display format (single and various combinations), to activate zoom features, and to utilize the cine loop function.

The SA-9900 uses digital beamforming technology, and supports a variety of Linear, Convex, Phased Array and Static probes for a wide variety of applications. It is an ultrasound scanner, which provides high resolution, high penetration performance, and various measurement functions. Probes are supported in frequencies from 1.0 MHz to 20.0 MHz. These probes can be applied to a variety of clinical applications such as fetal, abdominal, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-rectal, trans-vaginal, peripheral-vascular, muscular-skeletal. The same clinical uses were cleared for the predicate device, SA8800/HDI1500 (K974269)

The system can be used to measure distances and calculate areas, circumferences and volumes, as well as calculate the expected date of delivery by using BPD (biparietal diameter), OFD (occipitofrontal diameter), HC (head circumference), AC (abdominal circumference), AD (abdominal diameter), FL (femur length), CRL (crown rump length), APTD (anteroposterior trunk diameter), TTD (transverse trunk diameter), GS (gestational sac), LMP (last menstural period.), Cardiac Analysis (volume by area/length, Simpson biplane and single plane, M-mode analysis, Doppler: peak and mean gradients, pressure half time, E/A ratio and continuity equation) and Vascular Analysis (resistive index, pulsatility index, % stenosis, ICA/CCA ratio, Volume flow).

Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. M-mode uses the scroll display method which has its images flow from the right to the left on the monitor. The SA9900 supports the Cine function (capable of storing up to 256 sequential images) and real-time zoom function to the region-of-interest. The system provides the ability to perform remote viewing of images, without compression, via a DICOM 3.0 compatible output. Management of patient history is possible by image-filing function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing.

The SA9900 has been designed to meet the following electromechanical safety standards:

- EN 60601-1 (IEC 60601-1,) European Norm, Medical Electrical Equipment
- UL 2601-1, Underwriters Laboratories Standards, Medical Electrical Equipment
- C22.2 No. 601.1, Canadian Standards Association, Medical Electrical Equipment
- CEI/IEC 61157:1992, International Electrotechnical Commission, Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment
- EN 60601-1-2 (IEC 60601-1-2,) European Norm, Collateral Standard: Electromagnetic Compatibility
- Compliant with the European Medical Device Directive Certificate issued by TUV.

5) Intended Use:

SA9900 intended uses as defined FDA guidance documents are:

〈 Fetal (including infertility monitoring of follicle development)

〈 Abdominal

〈 Intra-operative (Abdominal, Vascular)

〈 Intra-operative (Neurological)

〈 Pediatric

〈 Small Organ

〈 Neonatal Cephalic

〈 Adult Cephalic

〈 Trans-rectal

〈 Trans-vaginal

〈 Trans-esophageal (Non cardiac, Cardiac)

〈 Muscular-skeletal (Conventional, Superficial)

〈 Cardiac (Adult, Pediatric)

〈 Peripheral-vascular

Typical examinations performed using the system are:

〈 General abdominal and pelvic studies including organ surveys, assessment, and retro-peritoneal cavity studies.

〈 Study of small parts including breasts, shoulders, thyroid, and the abdominal wall.

〈 Pediatric scans of organs and bony structures.

〈 Peripheral vascular applications including carotid arteries, legs, arms, feet, and penile artery.

〈 Monitoring procedures for infertility studies (other than in vitro fertilization).

〈 First, second and third trimester pregnancy studies.

〈 Prostate, prostate biopsy guidance, and rectal wall studies.

〈 Neonatal head studies.

〈 Transcranial studies of middle cerebral arteries, internal carotid artery, and vertebral arteries.

〈 Cardiac studies in adults and children.

〈 Biopsy guidance for tissue or fluid sampling.

- Conventional podiatry scans.
- Intra-operative application including soft tissue structures.

6) **Technological Characteristics:**

This device operates identical to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D and M-mode, Continuous wave Doppler, Spectral Doppler, Color Doppler, Power Doppler, 3D images. Transducer patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:	
	(Maximum Range)
I_{SPTA}	720 mW/cm2
MI	1.9

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2001

Medison America, Inc.
% Mr. Mark Job
Program Manager
TUV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K012867
Trade Name: SonoAce SA-9900 Diagnostic Ultrasound System
Regulatory Class: II/21CFR 892.1550
Product Code: 90 IYN
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Dated: August 24, 2001
Received: August 27, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoAce SA-9900 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

MPT4-7AL/4.0-7.0 MHz/Phased Array
CL4-8EV/4.0-8.0 MHz/Curved Linear Array
L15-9EV/5.0-9.0 MHz/Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations

affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

4.3 INDICATIONS FOR USE

DIAGNOSTIC ULTRASOUND INDICATIONS STATEMENT

510(k) No.:
System: SA9900 Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P	P	P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P	P	P	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*	N	N	N		N	Note 1	Notes 2, 7, 8
	Intra-operative (Neuro.)	N	N	N	N	N	Note 1	Notes 8
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note 1	Notes 2, 7, 8
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Notes 2, 8
	Neonatal Cephalic	P	P	P	P	P	Note 1	Notes 7, 8
	Adult Cephalic	P	P	P	P	P	Note 1	Notes 7, 8
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 8
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	N	N	N	N	N	Note 1 (N)	Notes 7, 8 (N)
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Notes 2, 8
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Notes 2, 8
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Notes 4,7, 8
	Cardiac Pediatric	P	P	P	P	P	Note 1	Notes 4,7, 8
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note 1 (N)	Notes 7, 8 (N)
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K002185; E= added under Appendix E

Additional Comments:
Color Doppler includes Color Amplitude Doppler (P)
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Dopppler (P)
Note 2: Includes imaging for guidance of biopsy (P)
Note 3: Includes infertility monitoring of follicle development (P)
Note 4: Color M-mode (P)
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P)
Note 6: Abdominal organs and peripheral vessel (P)
Note 7: Tissue Harmonic Imaging (THI) (P)
Note 8: 3D Imaging (P)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012867

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: SA9900 Ultrasound System
Transducer: **MPT4-7AL /4.0-7.0 MHz/Phased Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	N	N	N	N	N	Note 1 (N)	Notes 7, 8 (N)
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note 1 (N)	Notes 7, 8 (N)
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012867

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Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)	N	N	N		N	Note 1	Notes 2, 7, 8
	Intra-operative (Neuro.)	N	N	N	N	N	Note 1	Notes 8
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
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	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

David A. Simpson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012867

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	Intra-operative (Neuro.)	N	N	N	N	N	Note 1	Notes 8
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	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
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Note 7: Tissue Harmonic Imaging (THI) (P)
Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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and Radiological Devices
510(k) Number K012867